DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 19, 2016

Medtronic
Debra Taitague
Regulatory Affairs Specialist
1801 East Deere Ave
Santa Ana, California 92705

Re: K161249
Trade/Device Name: Streamline 6495 Bipolar Temporary Myocardial Pacing Lead
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent Or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: July 20, 2016
Received: July 21, 2016

Dear Debra Taitague:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161249

Device Name
Streamline 6495 Bipolar Temporary Myocardial Pacing Lead

Indications for Use *(Describe)*
The Streamline 6495 Bipolar Temporary Myocardial Pacing Lead is designed for temporary postsurgical atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and intended for single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

7.0 510(k) Summary

Date Prepared: May 02, 2016

Applicant:
Medtronic
Medtronic Heart Valve Division
1851 East Deere Ave
Santa Ana, CA 92705

Contact Person:
Debra Taitague
Regulatory Affairs Specialist
Medtronic
Phone: (234) 248 4186
Fax: (949) 553 8983
Email: debra.a.taitague@medtronic.com

Alternate Contact
Donna Saito
Sr. Regulatory Affairs Manager
Medtronic
Phone: (949) 399 1675
Fax: (949) 553 8983
Email: donna.y.saito@medtronic.com

Trade Name:	Streamline 6495 Bipolar Temporary Myocardial Pacing Lead Electrode
Classification Name:	Temporary Pacing Lead
Regulation Number:	21 CFR 870.3680(a)
Product Classification:	Class II
Product Code:	LDF
Name of Predicate Device	Streamline 6495 Bipolar Temporary Myocardial Pacing Lead

Device Description

The Streamline 6495 Bipolar Temporary Myocardial Pacing Lead consists of an insulated multi-filament lead (see **Figure 1**) which contains a distal, discrete, ring electrode (1), a discrete, tip electrode (2); and a coaxial conductor lead body (3). Each discrete electrode is crimped onto a conductor and terminates in an atraumatic, myocardial curved needle (4). A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue. An atraumatic chest needle (5) at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall.

Terminated on the back of the chest needle are two breakaway connector pins (6). To remove the pacing lead, gentle traction should be applied. No part of the lead remains in the body.

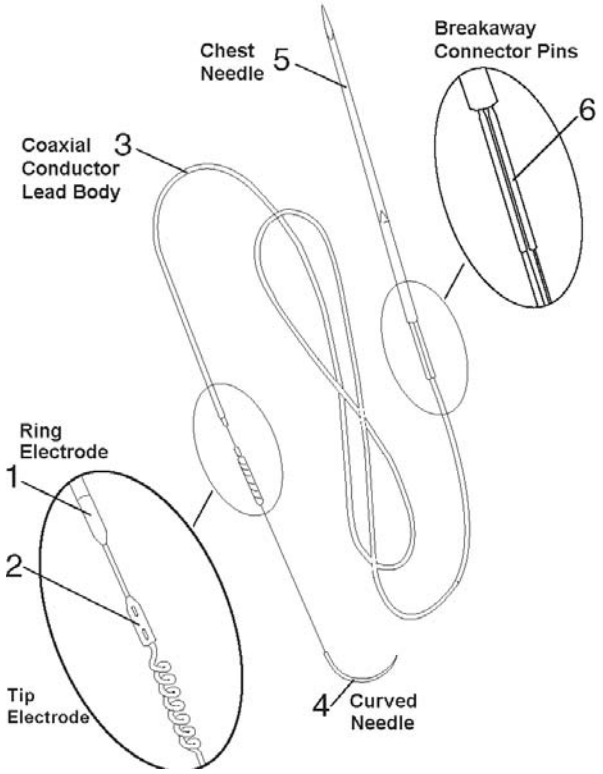

Figure 1: Model 6465

Indication for Use

The Streamline 6495 Bipolar Temporary Myocardial Pacing Lead is designed for temporary post-surgical atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and intended for single use only.

Contraindications

There are no known general contraindications to temporary postsurgical pacing. The particular medical condition and anatomy of the patient, however, may dictate the lead system and implantation procedure to be used.

Comparison to Predicate Device

A comparison of the Streamline 6495 Bipolar Temporary Myocardial Pacing Lead is being made to the current marketed predicate device: the Streamline 6495 Bipolar Temporary Myocardial Pacing Lead and listed below indicates the following similarities:

- Intended Use: The intended use is the same as the predicate
- Performance: The performance is substantially equivalent to the predicate device.
- Principles of Operation and Technology: The principles of operation are the same as the predicate device.
- Design: The overall design is the same as the predicate features

- Materials: The material types used are the same as the predicate

Description of Change

The purpose of this Premarket notification submission is to notify FDA of the proposed material change made to the formulation of the shrink band material. The current supplier, Vesta Thermoplastic Division informed Medtronic that their raw material supplier will no longer provide them with the raw material resins.

Summary of Testing

Testing has demonstrated that the Streamline 6495 Bipolar Temporary Myocardial Pacing Lead is substantially equivalent to the predicate. Presented in **Table 7-1** are the tests conducted:

Table 7-1: Tests conducted

Component	Base Material Change	Verification Validation	Results
Shrink Band	Current: Polyolefin Proposed: Polyolefin	Biocompatibility	Passed
		Manufacturability	Passed

Conclusion

The data included in this submission is sufficient in providing reasonable assurance of the safety and effectiveness of the device and the Streamline 6495 Bipolar Temporary Myocardial Pacing lead is substantially equivalent to the legally marketed predicate device, the Streamline 6495 Bipolar Temporary Myocardial Pacing Lead.